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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,340	11/13/2001	Jonathan David Kurtis	22493-501 (SYMB-1)	3426

7590 07/20/2004

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,340	KURTIS ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1632.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 4-15 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

As amended, claims 2 and 4-15 are directed to male helminthes produced by a process of stably and heritably transfecting germ line cells in the ovary of a female helminth with nucleic acid of carried in an adeno-associated vector. The specification provides no working example or demonstration of such a method. The prior art is devoid of such a method. Xiao et al. (Adv. Drug Deliv. Rev. 12: 201-215, 1993) discloses that the host range of adeno-associated viruses is limited to warm-blooded vertebrates, i.e. birds and mammals (pages 203, 210). The examiner was unable to identify any art, much less prior art, disclosing the successful transfection of helminth cells with AAV or an AAV vector, either *in vitro* or *in vivo*. The invention, as claimed,

is inoperative because the AAV vector would not transfect any helminth cells, much less germ line cells, and the male progeny would not be made.

Claim Rejections - 35 USC § 112

Claims 2 and 4-15 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 11/5/03 and the new reasons set forth below, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As amended, the male helminth is required to be made by a process that is inoperative for reasons set forth in the rejection under §101. Therefore, the specification does not teach how to make the claimed male helminth.

Applicant's arguments filed 5/12/04 have been fully considered but they are not persuasive. Applicant asserts that the specification provides the necessary teachings, and asserts that Miller generally teaches how to transform helminthes. The rejection of record sets forth the reasons that the specification fails to provide an enabling teaching. The primary reason is that the specification presents goals - the products, but fails to provide specific guidance on how to make the claimed products. The disclosure of Miller is not at issue. Also, Miller does not "generally" teach transformation of helminthes, it is a prophetic disclosure of how to make transgenic schistasomes.

If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet

enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See *Genentech Inc. v. Novo Nordisk A/S,* 42 USPQ2d 1001, 1997.

Claims 2 and 4-15 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 11/5/03 and the new reasons set forth below, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As amended, the male helminth is required to be made by a process that is inoperative for reasons set forth in the rejection under §101. One cannot be in possession of a product that cannot be made.

Applicant's arguments filed 5/12/04 have been fully considered but they are not persuasive. Applicant argues that the general guidance in the specification on making the claimed male helminthes demonstrates possession and satisfies the written description requirement. However, the specification at best prophetically discloses a general method for making the claimed products. It does not however disclose any product actually made, nor does it provide a description of the nucleic acid required to produce the male helminth. This nucleic acid must not only encode a heterologous protein, but must include those regulatory sequences that would permit it to be expressed in the helminth and whatever sequences are required to direct its secretion out of the helminth. Without this detail, one cannot envision the worm being made.

The reliance on *Amgen* here is unclear. The decision published by BNA in USPQ2d includes headnotes but no opinion text. From the headnotes (para. 5), it appears that the issue Applicant is referring to was whether the claims failed written description for failing to adequately describe endogenous EPO coding sequence found in cells used to express human EPO, whereas the invention was recombinant expression of human EPO in such cells, i.e. the sequence of the endogenous EPO coding sequence of the host cells was not relevant to the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe
Primary Examiner
Art Unit 1632